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10/686,083	10/15/2003	Narayan Sundararajan	42P13833D	7275

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/686,083

Applicant(s)

SUNDARARAJAN ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-22 is/are rejected.
- 7) ☒ Claim(s) 4 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 2 June 2006 in which claims 1-4, 7-8, 10, 13, 16, 18-19, 22 were amended and claim 9 was canceled. the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 3 March 2006, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by amendment, are discussed.

Claims 1-8 and 10-22 are under prosecution.

Claim Objections

2. Claims 4 and 7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim defines DNA and RNA precursors that are incorporated into the immobilized nucleic acids during use of the apparatus of Claim 3. Claim 3 defines the apparatus of Claim 1 as having polymerase in the chamber. The claim further describes an intended use of the polymerase i.e. incorporate DNA or RNA precursors. However, the precursors are not a component of the claimed apparatus. Therefore, defining the precursors does not further define the apparatus.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 5-6, 8, 10-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Baller et al (WO 01/33226, published 10 May 2001).

Regarding Claim 1, Baller et al disclose an apparatus comprising a analysis chamber (Fig. 8) containing one or more cantilevers (#102) each comprising one or more covalently attached nucleic acid templates (thiol modified DNA attached to gold-coated cantilever, page 13, lines 9-15) wherein the cantilevers are responsive to deflection produced by changes in mass (i.e. addition of complementary sequence adds mass to the cantilever and causes deflection, page 13, lines 1-20), one or more reagent reservoirs in fluid communication with the chamber (i.e. input #112/output #113, Fig. 8), a detection unit operably coupled to the cantilever (PSD, #108) and a data processing and control unit "operably coupled" to the chamber, reservoirs and detection unit (PC #111, Fig. 8).

Regarding Claim 2, Baller et al disclose the apparatus wherein the nucleic acids are about 10 nucleotides in length (e.g. 12 and 16 mer, page 12, lines 18-23).

Regarding Claim 5, Baller et al disclose the apparatus wherein the detection unit comprises a piezoresistor (page 7, lines 15-22).

Regarding Claim 6, Baller et al disclose the apparatus wherein the detection unit comprises a laser (page 7, lines 23-25).

Regarding Claim 8, Baller et al disclose an apparatus comprising a analysis chamber (Fig. 8) containing one or more cantilevers (#102) each comprising one or more covalently attached nucleic acid templates (thiol modified DNA attached to gold-coated cantilever, page 13, lines 9-15) wherein the cantilevers are responsive to deflection produced by changes in mass (i.e. addition of complementary sequence adds mass to the cantilever and causes deflection, page 13, lines 1-20), a detection unit operably coupled to the cantilever (PSD, #108)

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and a data processing and control unit “operably coupled” to the chamber, reservoirs and detection unit (PC #111, Fig. 8).

Regarding Claim 10, Baller et al disclose the apparatus wherein the data processing and control unit is a computer (PC #111, Fig. 8).

Regarding Claim 11, Baller et al disclose the apparatus wherein the detection unit comprises a laser and a position sensitive photo detector (page 15, line 28-page 16, line 1).

Regarding Claim 12, Baller et al disclose the apparatus wherein the detection unit comprises a piezoresistor (page 7, lines 15-22).

Regarding Claim 13, Baller et al disclose the apparatus wherein the nucleic acids are about 10 nucleotides in length (e.g. 12 and 16 mer, page 12, lines 18-23).

Regarding Claim 14, Baller et al disclose the apparatus further comprising an array of cantilevers (#102) wherein each cantilever is “associated with the same molecule”.

The claims are given the broadest reasonable interpretation consistent with the broad claim language and specification wherein “associated with” is not defined. The apparatus of Baller has an array of cantilevers within a liquid cell having an inlet for fluid flow into the cell. The cell is used e.g. hybridization. Any molecule (e.g. buffer molecules) put into the cell via the inlet would be “associated with” each cantilever as claimed.

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

Regarding Claim 15, Baller et al disclose the apparatus further comprising an array of cantilevers (#102) wherein each cantilever is “associated with a different molecule” i.e. have different affinities for a target (page 8, lines 24-27; page 11, lines 14-20; and page 12, lines 18-23).

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Regarding Claim 16, Baller et al disclose an apparatus comprising a analysis chamber (Fig. 8) containing one or more cantilevers (#102) each comprising one or more covalently attached nucleic acid templates (thiol modified DNA attached to gold-coated cantilever, page 13, lines 9-15) wherein the cantilevers are responsive to deflection produced by changes in mass (i.e. addition of complementary sequence adds mass to the cantilever and causes deflection, page 13, lines 1-20), a piezoresistor embedded at the fixed end of the cantilever (page 7, lines 15-22), a detection unit "operably coupled" to the piezoresistor to detect deflection (page 7, lines 15-22) and a data processing and control unit "operably coupled" to the chamber, reservoirs and detection unit (PC #111, Fig. 8).

Regarding Claim 17, Baller et al disclose the apparatus further comprising a resistance measuring device (page 7, line 18).

Regarding Claim 18, Baller et al disclose the apparatus wherein the nucleic acids are about 10 nucleotides in length (e.g. 12 and 16 mer, page 12, lines 18-23).

Regarding Claim 22, Baller disclose the apparatus wherein the nucleic acids are coupled to the cantilever through a thiol group (page 13, lines 9-15).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 3-4, 7, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baller et al (WO 01/33226, published 10 May 2001) in view of Melamede, (EP 0233618 A2, published 27 May 1987).

Regarding Claims 3-4, 7, Baller et al disclose an apparatus comprising a analysis chamber (Fig. 8) containing one or more cantilevers (#102) each comprising one or more covalently attached nucleic acid templates (thiol modified DNA attached to gold-coated cantilever, page 13, lines 9-15) wherein the cantilevers are responsive to deflection produced by changes in mass (i.e. addition of complementary sequence adds mass to the cantilever and causes deflection, page 13, lines 1-20), one or more reagent reservoirs in fluid communication with the chamber (i.e. input #112/output #113, Fig. 8), a detection unit operably coupled to the cantilever (PSD, #108) and a data processing and control unit "operably coupled" to the chamber, reservoirs and detection unit (PC #111, Fig. 8). Baller et al disclose the apparatus wherein the cantilevers function to detect biomolecule binding (page 9, lines 22-24) and are useful for determining base sequence analysis (page 13, lines 22-25) but they are silent regarding addition of polymerase to the analysis chamber. However, addition of a polymerase to an analysis chamber having immobilized template for the analysis of base sequence was well known and routinely practiced in the art as taught by Melamede. Melamede teaches that addition of the polymerase to an immobilized template allows for movement of the polymerase and precursors to and from the template for nucleotide incorporation for the analysis of base sequence during incorporation (Column 12, line 55-Column 13, line 30). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polymerase of Melamede to the apparatus of Baller et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of automated analysis of base sequence during nucleotide addition as desired in the art as taught by Melamede (Column 7, lines 44-46).

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As stated above, the limitations of intended use (i.e. incorporation of DNA or RNA precursor and detection of the mass produced from the incorporation) do not further define the apparatus over the prior art. The courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Because the prior art teaches the elements of Claim 3, the prior art also teaches the structural elements of Claims 4 and 7.

Regarding Claim 19, Baller et al disclose an apparatus comprising a analysis chamber (Fig. 8) containing one or more cantilevers (#102) coated with a substance (e.g. gold layer, page 13, lines 13-15) each comprising one or more covalently attached nucleic acid templates (thiol modified DNA attached to gold-coated cantilever, page 13, lines 9-15) wherein the cantilevers are responsive to deflection produced by changes in mass (i.e. addition of complementary sequence adds mass to the cantilever and causes deflection, page 13, lines 1-20) a detection unit operably coupled to the cantilever (PSD, #108) and a data processing and control unit "operably coupled" to the chamber, reservoirs and detection unit (PC #111, Fig. 8).

Baller et al disclose the apparatus wherein the cantilevers function to detect biomolecule binding (page 9, lines 22-24) and are useful for determining base sequence analysis (page 13, lines 22-25) but they are silent regarding addition of polymerase to the analysis chamber. However, addition of a polymerase to an analysis chamber having immobilized template for the analysis of base sequence was well known and routinely practiced in the art as taught by Melamede. Melamede teaches that addition of the polymerase to an immobilized template allows for movement of the polymerase and precursors to and from the template for nucleotide incorporation for the analysis of base sequence during incorporation (Column 12, line 55-Column 13, line 30). It would have been obvious to one of ordinary skill in

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the art at the time the claimed invention was made to apply the polymerase of Melamede to the apparatus of Baller et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of automated analysis of base sequence during nucleotide addition as desired in the art as taught by Melamede (Column 7, lines 44-46).

Regarding Claim 20-21, Baller et al disclose the substance is an alloy e.g. gold (page 13, lines 9-15).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-8, 10-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-17, 19-20, 29-30, 34-37, 42-52 of copending Application No. 10/254,201 in view of Lindsay et al (U.S. Patent No. 5,750,989).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an apparatus comprising cantilever structures, detection unit and data processing/control unit. The claim sets merely differ in

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that the instant claims define the cantilever as part of an analysis chamber. While the '083 claims do not require a chamber, cantilevers chambers were well known and routinely practiced in the art at the time the claimed invention was made as taught by Lindsay et al who teach that the chamber permits sample analysis within a controlled environment (Column 4, lines 12-34). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the chamber of Lindsay et al to the '083 apparatus for the expected benefit of environmentally controlled sample analysis as desired in the art (Lindsay et al, Column 4, lines 12-34). The claim sets further differ in that the '201 claims require a dielectric sphere, laser and objective lens. However, the instant claim language "comprising" encompasses the additional elements recited in the '201 claims. For these reasons, the claim sets are not patentably distinct.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

9. Applicant asserts that the '201 claims require additional elements not recited in the instant claims i.e. dielectric sphere, laser and objective lens. The argument has been considered but is not found persuasive because, as state above, the instant claim language "comprising" encompasses the additional elements recited in the '201 claims. The rejection is maintained.

10. Claims 1-8 and 10-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-46 of copending Application No. 10/705,389 as evidenced by Fritz et al (Science, 2000, 288: 316-318). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an apparatus comprising cantilever structures, detection unit and data processing/control unit. The claim sets merely differ in the arrangement of

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limitations within the claim sets and terminology used to define some elements. For example, the instant claims define the nucleic acids as being covalently attached to the cantilever while the '389 claims define the nucleic acid as being attached via a thiol group to a gold surface (e.g. Claims 44-45). Fritz et al define the thiol-gold attachment as covalent (page 318, right column ¶ 15). Therefore, the instantly claimed apparatus and that of the '389 claim set are not patentably distinct.

Response to Arguments

11. Applicant asserts that the amendments present claims that are no longer co-extensive in scope. The assertion is noted. The claims are rejected as discussed above.

This is a provisional obviousness-type double patenting rejection.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
August 10, 2006